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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,032	04/26/1999	GUY SERRE	3339-392	6404

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
MAYES, LAURIE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/254,032	Applicant(s) SERRE ET AL.	
	Examiner Laurie Mayes	Art Unit 1653	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The certified copy of application PCT/FR97/01541 has been entered into the record.

The abstract on a separate sheet is acceptable and has been entered into the record.

The rejection of claim 5 under 35 U.S.C. 101 is withdrawn based upon the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 remain rejected and claims 11 and 12 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the claim recites that at least one arginine residue is replaced by a citrulline residue; however, claim 1 fails to refer to the corresponding sequence identifier (SEQ ID NO:). The applicant amended the claim by inserting a reference to an amino acid residue having at least one arginine. However, it is unclear whether filaggrin contains more than one arginine residue and whether there would be any unexpected changes and/ or properties based on random changes of arginine to citrulline, for example.

The language "derived from" in claims 1 and 2-12, dependent on claim 1, is unclear as to whether or not the claimed antigen derived from has or does not have four consecutive amino acid residues identical to that of filaggrin. The language "derived from" does not necessarily equate to identity. In this instance, the four of the five amino acid residues can be any sequence

and need not actually be that from filaggrin since use of "derived from" means in one instance, that the amino acid residues may have come from any peptide.

Claim 2 recites "amino acids 144 to 314 of a human filaggrin unit" and "amino acids 76 to 144" of a human filaggrin unit without the corresponding sequence identifier (SEQ ID NO:). In addition, the claim recites "amino acids" rather than "amino acid residues". The applicant argues that the sequences recited in claim 2 refer to the sequence of human filaggrin, which is known to one skilled in the art, and therefore there is no need to identify such a sequence. However, a sequence identifier is still required as it is unclear whether there is a different numbering scheme for different filaggrin, for example. Also, the language "derived from" and "corresponding to" does not necessarily equate to identity. Again, the four of the five amino acid residues can be any sequence and need not actually be that from filaggrin since use of "derived from" means in one instance, that the amino acid residues may have come from any peptide. Further, the 238 amino acids referred to could be from a peptide other than filaggrin. In addition, it is unclear whether the language "corresponding to" means conservative substitutions.

Claim 3 is unclear as to what is the "or part of at least one sequence" of SEQ ID NO: 3. It is unclear whether it is the part which is defined by residues 144-314, 1-143, 76-144, or 1-75 or some subfragment.

Similarly, Claim 4 is unclear as to what is the "or part of at least one sequence" of SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 6.

Claim 5 is rejected as it depends from rejected base claims 1-4.

Claim 6 contains an intended use phrase ". . . for diagnosing the presence of autoantibodies specific for rheumatoid arthritis in a biological sample . . ." which bears no

patentable weight. The claim is unclear as to recitation of ". . . at least one antigen . . ." since claims 1-4 refer to antigen in the singular, see e.g., "An artificial antigen . . ." (claim1, line 1); and "The artificial antigen . . ." (claim 2, line 1).

Claims 11 and 12 are rejected as depending from rejected base claims and do not rectify the reasons for holding indefiniteness set forth above.

Applicant's commentary in the response filed on 25 July 2002 have been considered but are unpersuasive. Applicant's response at page 4 asserts various corrections but do not appear to address the above stated rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6 ~~1, 5 and 6~~ remain rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al. for reasons of record Simon teaches an antigen that is recognized by the antifilaggrin

autoantibodies found in patient with rheumatoid arthritis (p. 1391, col. 2, first full paragraph) and consists of a polypeptide comprising at least five consecutive amino acid residues, at least one being an arginine residue, of a sequence derived from that of a filaggrin unit (p. 1391, col. 2, last paragraph), by replacing at least one arginine residue with a citrulline residue. (p. 1391, col. 2, last paragraph), and a method for the in vitro diagnosis of rheumatoid arthritis comprising the steps of providing the antigen of claim 1 (p. 1391, col. 2, first full paragraph), providing a human skin sample for diagnosis of rheumatoid arthritis (p. 1391, col. 2, first full paragraph), bringing the skin sample into contact with the antigen allowing the formation and detection of an antigen/ antibody complex (p. 1391, col. 2, first full paragraph), and a SDS-PAGE buffer, gel, water and reagents appropriate for allowing the formation of an antigen/ antibody complex. (p. 1388, figure 1)

Simon also teaches an antigenic composition for diagnosing the presence of antibodies specific for rheumatoid arthritis in a human sample which contains the antigen in claim 1, with the exclusion of compositions with a structure identical to that of filaggrin which is purified from the human epidermis comprising a mixture of isoforms having a molecular weight of 40,000 and a pI of between 5.8 and 7.4. (p. 1389, col. 1, first paragraph) Thus claims 1, 5 and 6 are anticipated by this reference.

The applicant argues that Simon et al. does not anticipate any of the applicant's pending claims because Simon's antigens consist of a mixture of polypeptides of a different sequence purified from human epidermis while the claimed antigens are homogeneous prepararations resulting from a recombinant filaggrin fragment. However, the applicant is reminded that once synthesized, one cannot determine the origin of the peptide. Therefore the artificial antigen of

claim 1 is anticipated by the purified antigen taught by Simon et al. Claims 2-4 are rejected as dependent on rejected claim 1. It is noted that a degree of purity which distinguishes the instant peptide from that of Simon et al. may be sufficient to overcome the reference.

Claims 6, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Serre et al (United States Patent Number 5,888,833). Serre teaches antigens from human and rat cells that are recognized by the autoantibodies directed against filaggrin where the basic arginine residues are converted to citrulline residues. (col. 5, line) Serre also teaches the labeling or conjugation to a carrier molecule of these antigens (col. 8, lines 47-49). Thus the claims 6, 11 and 12 are anticipated by this reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6 and 11-12 rejected under the judicially created doctrine of double patenting over claim 2 of U. S. Patent No. 5,888,833 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter,

as follows: the antigen in the application is obvious over the purified components of the kit in claim 2 of the patent. The antigens in the kit from rat cells are recognized by the autoantibodies directed against filaggrin where the basic arginine residues are converted to citrulline residues. These antigens may also be labeled or conjugated to a carrier molecule. Thus, the antigens in claims 6, 11 and 12 in the application are obvious over the antigens in the patent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached from Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
October 21, 2002

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600